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Shinn-Gwo Hong

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Supreme Patent Services  
Post Office Box 2339  
Saratoga, CA 95070-0339

EXAMINER

STULTZ, JESSICA T

ART UNIT

PAPER NUMBER

2873

DATE MAILED: 08/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/620,783

Applicant(s)

HONG, SHINN-GWO

Examiner

Jessica T Stultz

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-32 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- 1) ☒ Certified copies of the priority documents have been received.
  - 2) ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_.

## DETAILED ACTION

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 5-8, 10-11, 13-21, 23, 25-31 are rejected under 35 U.S.C. 102(b) as being anticipated by Lally et al.

Regarding claims 1 and 28, Lally et al discloses a reactive tinting compound and method of preparing a reactive tinting compound for tinted contact lens (Column 1, lines 7-11 and Column 3, lines 34-57, wherein a polymeric article and a dye are reacted to form a tint for contact lenses) comprising the step of: carrying out a reaction of a first compound with a second compound to generate a product of reactive tinting compound (Column 1, lines 7-11 and Column 3, lines 34-57, wherein the first compound is a polymeric article, either a polymeric precursor or prepolymer and the second compound is a radiation-absorbing dye are reacted to form a reactive tint for contact lenses), wherein the first compound is a hydrophilic compound with pendant hydroxyl and unsaturated vinyl groups (Column 8, line 59-Column 9, line 61, wherein the prepolymer is either methacrylamide, hydroxyethyl acrylate, or n-vinylpyrrolidone, which are all hydrophilic compounds with pendant hydroxyl and unsaturated vinyl groups), and the second compound is a radiation-absorbing and water soluble dye with substituted beta-sulphatoethylsulphone reactive group (Column 15, lines 6-52, wherein the radiation-absorbing dyes are beta-sulphatoethylsulphone derivative, specifically Reactive Yellow 15, Reactive Blue

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19 and Reactive Blue 21); and recovering the product after the reaction is complete (Column 1, lines 7-11 and Column 3, lines 34-57 and Figure 2, wherein the prepolymerization mixture is recovered and then dispensed into a lens mold).

Regarding claim 2, Lally et al further discloses that the molar ratio of the first compound to the second compound is 1/1 to 5/1 (Column 13, lines 10-35).

Regarding claim 3, Lally et al further discloses that the first compound is hydroxyl ethyl acrylate (Column 8, line 59-Column 9, line 61, wherein the prepolymer is hydroxyethyl acrylate).

Regarding claim 5, Lally et al further discloses that the second compound is substituted beta-sulphatoethylsulphone reactive group, specifically Reactive Yellow 15, Reactive Blue 19, or Reactive Blue 21 (Column 15, lines 6-52, wherein the radiation-absorbing dyes are beta-sulphatoethylesulphone derivative, specifically Reactive Yellow 15, Reactive Blue 19 and Reactive Blue 21).

Regarding claim 6, Lally et al further discloses the steps of preparing a mixture of a first compound, a base compound, and a polymerization inhibitor in water (Column 20, lines 31-54, Figure 2, wherein the polymer precursor functionalizer is mixed with the prepolymer, wherein the polymer precursor includes an inhibitor, water, and a base compound, specifically sodium hydroxide); mixing the second compound with the mixture of the first step (Column 20, lines 18-26, wherein the functionalization of the dye includes diluting Blue 19 in water), and initiating a synthesis reaction of the reactive tinting compound under heating (Column 21, lines 24-32, wherein cross linking of the dye and the prepolymer occurs due to heating).

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Regarding claim 7, Lally et al further discloses that the molar ratio of the first compound to the second compound is 1/1 to 5/1 (Column 13, lines 10-35).

Regarding claim 8, Lally et al further discloses that the first compound is hydroxyl ethyl acrylate (Column 8, line 59-Column 9, line 61, wherein the prepolymer is hydroxyethyl acrylate).

Regarding claim 10, Lally et al further discloses that the base compound is an alkaline metal hydroxide (Column 20m, lines 31-54, wherein the base compound is sodium hydroxide, i.e. and alkaline metal hydroxide).

Regarding claim 11, Lally et al further discloses that the molar ratio of the base compound to the second compound is 1/1 to 5/1 (Column 20, line 15-Column 21, lines 32).

Regarding claim 13, it is inherent from Lally et al further discloses that the polymerization inhibitor is 0.02 to 3% of the first compound, this being reasonably based upon the addition of a minimal amount of the inhibitor (Column 20, line 28-Column 21, line 21,w herein the first compound is the purified cross linkable prepolymer which contains only 50 mg of the inhibitor).

Regarding claim 14, Lally et al further discloses that the reaction is at 50 to 100 degrees Celsius (Column 21, lines 24-32, wherein the reaction occurs between 25-60 degrees Celsius).

Regarding claim 15, Lally et al further discloses that the reaction is for 12-24 hours (Column 20, line 9-Column 21, line 32, wherein the preparation of the cross linkable polymer takes 20 hours).

Regarding claim 16, Lally et al further discloses the steps of activating the second compound with a base compound in water (Column 20, lines 18-26, wherein the Reactive Blue

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19 is mixed with a base compound, specifically sodium carbonate, and water); mixing the first compound with the resulting mixture of the previous step (Column 20, line 15-Column 21, line 32, wherein the functionalized dye is mixed with the first compound, i.e. the prepolymer); optionally mixing a polymerization inhibitor with the mixture of the previous step and initiating a synthesis reaction of the reactive tinting compound (Column 20, line 31-Column 21, line 32, Figure 2, wherein the polymer precursor functionalizer is mixed with the prepolymer, wherein the polymer precursor includes an inhibitor and wherein the dye and prepolymer are mixed to form a reactive tinting compound).

Regarding claim 17, Lally et al further discloses that the activating step is at 30 to 80 degrees Celsius (Column 15, line 41-Column 16, line 19, wherein the activation temperature is 30-50 degrees Celsius).

Regarding claim 18, Lally et al further disclose that the activating step is about 10-45 minutes, which falls within the range of 0.5 to 4 hours (Column 20, lines 18-26).

Regarding claim 19, Lally et al further discloses that the molar ratio of the first compound to the second compound is 1/1 to 5/1 (Column 13, lines 10-35).

Regarding claim 20, Lally et al further discloses that the first compound is hydroxyl ethyl acrylate (Column 8, line 59-Column 9, line 61, wherein the prepolymer is hydroxyethyl acrylate).

Regarding claim 21, Lally et al further discloses that the second compound is substituted beta-sulphatoethylsulphone reactive group, specifically Reactive Yellow 15, Reactive Blue 19, or Reactive Blue 21 (Column 15, lines 6-52, wherein the radiation-absorbing dyes are beta-

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sulphatoethylesulphone derivative, specifically Reactive Yellow 15, Reactive Blue 19 and Reactive Blue 21).

Regarding claim 23, Lally et al further discloses that the molar ratio of the base compound to the second compound is 1/1 to 5/1 (Column 20, line 15-Column 21, lines 32).

Regarding claim 25, it is inherent from Lally et al further discloses that the polymerization inhibitor is 0.02 to 3% of the first compound, this being reasonably based upon the addition of a minimal amount of the inhibitor (Column 20, line 28-Column 21, line 21,w herein the first compound is the purified cross linkable prepolymer which contains only 50 mg of the inhibitor).

Regarding claim 26, Lally et al further discloses that the reaction is at room temperature to 50 degrees Celsius (Column 21, lines 25-32, wherein the reaction occurs between 25 to 60 degrees Celsius).

Regarding claim 27, Lally et al further discloses that the reaction is for 12-24 hours (Column 20, line 9-Column 21, line 32, wherein the preparation of the cross linkable polymer takes 20 hours).

Regarding claim 29, Lally et al further discloses a tinted contact lens comprising a hydrophilic monomer material (Column 18, line 43-Column 20, line 14, wherein the lens is made from cross linking with co monomers, i.e. hydrophilic monomers), an inert diluent (Column 20, lines 54-63, wherein the cross linking polymer is diluted with water), an acrylic cross linker with multiple unsaturated vinyl groups (Column 17, line 64-Column 20, line 14, wherein the lens is made using an acrylic cross linker) and a reactive tinting compound prepared by the steps comprising (Column 1, lines 7-11 and Column 3, lines 34-57, wherein a polymeric article and a

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dye are reacted to form a tint for contact lenses and Column 21, lines 35-45, wherein a tinted contact lens is formed): carrying out a reaction of a first compound with a second compound to generate a product of reactive tinting compound (Column 1, lines 7-11 and Column 3, lines 34-57, wherein the first compound is a polymeric article, either a polymeric precursor or prepolymer and the second compound is a radiation-absorbing dye are reacted to form a reactive tint for contact lenses), wherein the first compound is a hydrophilic compound with pendant hydroxyl and unsaturated vinyl groups (Column 8, line 59-Column 9, line 61, wherein the prepolymer is either methacrylamide, hydroxyethyl acrylate, or n-vinylpyrrolidone, which are all hydrophilic compounds with pendant hydroxyl and unsaturated vinyl groups), and the second compound is a radiation-absorbing and water soluble dye with substituted beta-sulphatoethylsulphone reactive group (Column 15, lines 6-52, wherein the radiation-absorbing dyes are beta-sulphatoethylsulphone derivative, specifically Reactive Yellow 15, Reactive Blue 19 and Reactive Blue 21); and recovering the product after the reaction is complete (Column 1, lines 7-11 and Column 3, lines 34-57 and Figure 2, wherein the prepolymerization mixture is recovered and then dispensed into a lens mold).

Regarding claim 30, it is inherent from Lally et al that the reactive tinting compound be 0.01 to 0.25 percent based on the weight of the hydrophilic monomer material, this being reasonably based upon the small amount of dye added to the cross linked solution (Column 21, lines 24-45, wherein 1 gram of dye is added to the purified cross linked solution and therefore the resultant lens would have 0.01 to 0.25 percent of reactive tinting).



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Regarding claim 31, Lally et al further discloses that he hydrophilic monomer material is hydroxyl ether methacrylate, methacrylic acid or n-vinyl pyrrolidone (Column 19, line 49-Column 20, line 8).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 4 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lally et al in view of Su et al.

Regarding claims 4 and 9, Lally et al discloses a method of making a reactive tinting compound as shown above, but does not specifically disclose that the second compound is substituted difluoro-chloropyrimidine Reactive Blue 114. Su et al teaches of a method of making a tinted contact lens (Abstract) wherein the dye used is Reactive blue 114 (See Table, Column 7) for the purpose of providing a reactive dye of any desired shade or tint with the necessary exoskeleton bond (Column 5, line 19-Column 6, line 40). Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made for the method of making a reactive tinting compound as disclosed above further include the second compound made of substituted difluoro-chloropyrimidine Reactive Blue 114 since Su et al teaches of a method of making a tinted contact lens wherein the dye used is Reactive blue 114 for the purpose of providing a reactive dye of any desired shade or tint with the necessary exoskeleton bond.

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Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lally et al.

Regarding claim 22, Lally et al discloses a method of making a reactive tinting compound as disclosed above wherein the dye is activated with a base compound, but does not specifically disclose that the base compound is an alkaline metal hydroxide, ammonia, or a salt of an alkaline. However Lally et al teaches of a using sodium hydroxide as a base compound, which is combined with the second compound for the purpose of lowering the pH of the polymer precursor (Column 20, lines 28-53). Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made for the base compound added to the first compound be an alkaline metal hydroxide since Lally et al teaches of a using sodium hydroxide as a base compound which is combined with the second compound for the purpose of lowering the pH of the polymer precursor.

Claims 12 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lally et al in view of Bawa.

Regarding claims 12 and 24, Lally et al discloses a method of making a reactive tinting compound as disclosed above, but does not specifically disclose that the polymerization inhibitor is hydroquinone. Bawa teaches of a tinted contact lens (Abstract) wherein hydroquinone is used as a polymerization inhibitor for the purpose of avoiding rapid curing or polymerization of the monomer (Column 3, lines 39-48). Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made for the method of making a reactive tinting compound of Lally et al to further include hydroquinone as the polymerization inhibitor since Bawa teaches of a tinted contact lens wherein hydroquinone is used as a polymerization inhibitor for the purpose of avoiding rapid curing or polymerization of the monomer.

Claim 32 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lally et al in view of Baba et al.

Regarding claim 32, Lally et al discloses a tinted contact lens as disclosed above, but does not specifically disclose that the acrylic cross linker is ethylene glycol dimethacrylate as the cross linker. Baba et al teaches of a contact lens wherein ethylene glycol dimethacrylate is used as the cross linking agent for the purpose of obtaining a highly safer ocular lens material with excellent mechanical strength (Column 12, line 65-Column 13, line 9). Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made for the tinted contact lens of Lally et al to further include ethylene glycol dimethacrylate as the cross linker since Baba et al teaches of a contact lens wherein ethylene glycol dimethacrylate is used as the cross linking agent for the purpose of obtaining a highly safer ocular lens material with excellent mechanical strength.

### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Muller et al is cited because it discloses a tinted contact lens formed by cross-linking agents.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica T Stultz whose telephone number is (571) 272-2339. The examiner can normally be reached on M-F 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Georgia Epps can be reached on 571-272-2328. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jessica Stultz  
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